

REMARKS

Summary of the Invention

The invention features a method for treating a patient suffering from oral aphthous by applying a composition consisting essentially of a topical anti-inflammatory steroid in combination with pentoxifylline (PTX) to the oral mucosa of the patient.

Summary of the Office Action

Claims 1-3 and 5-6 are pending. Claims 2 and 5 are withdrawn from consideration as being directed to a non-elected invention. Claims 1, 3, and 6 are rejected under 35 U.S.C. § 103 for obviousness over Andrulis et al. (U.S. Patent No. 5,654,312; hereinafter “Andrulis”) in combination with Quinn et al. (Stomatitis, Nov. 29, 1995; hereinafter “Quinn”). By this reply, Applicant amends claim 1 and addresses the Examiner’s rejection below.

Rejection under 35 U.S.C. § 103(a)

Andrulis and Quinn

Claims 1, 3, and 6 are rejected under 35 U.S.C. § 103(a) over Andrulis in combination with Quinn. The Examiner states:

One of ordinary skill in the art would have been motivated to employ the combination of TNF antagonists and steroids herein in the treatment of apthae because both TNF antagonist[s] and steroids are known to be useful in treating dermatoses with an autoimmune or inflammatory basis (e.g., oral apthae), and each of the agents herein employed are known to be useful for such treatment. (Office Action, p. 3.)

Applicant respectfully disagrees that the method of present claims 1, 3, and 6 is taught or suggested by Andrulis in combination with Quinn.

M.P.E.P. § 2143.03 states: “To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).” Andrulis in combination with Quinn fails to teach or suggest all of the limitations of claims 1, 3, and 6, as presently amended. Thus, the combination of these references fails to establish *prima facie* obviousness of the claimed invention.

Andrulis discloses administering a composition containing thalidomide alone or in combination with both pentoxifylline and a glucocorticoid, such as dexamethasone, to a patient for the treatment of a dermatological condition (see col. 9, lines 34-45). Andrulis fails to teach or suggest a composition containing pentoxifylline in the absence of thalidomide for treating aphthous.

Claim 1, as presently amended, recites a method of treating a patient suffering from aphthous by applying to the oral mucosa of the patient a composition that includes a topical anti-inflammatory steroid in combination with pentoxifylline. Applicant has amended claim 1 to specify that pentoxifylline is the only TNF- α inhibitor present in the composition, thus excluding thalidomide. Because Andrulis fails to teach or suggest a composition containing pentoxifylline as the only TNF- α inhibitor, Andrulis fails to teach or suggest all of the elements of present claims 1, 3, and 6. Accordingly, Andrulis alone fails to form the basis for a *prima facie* case of obviousness against claims 1, 3, and 6.

To remedy the deficiencies of Andrulis, the Examiner provides Quinn. The Examiner states that “Quinn...teaches that aphthae is cause [sic] by an underlying autoimmune mechanism.” (Office Action, p. 3). Quinn, like Andrulis, fails to teach or suggest a composition for treating aphthous that includes a topical anti-inflammatory steroid in combination with pentoxifylline as the only TNF- α inhibitor. Because neither Andrulis nor Quinn, either alone or

in combination, teaches or suggests applying a composition that includes a topical anti-inflammatory steroid in combination with pentoxifylline to the oral mucosa of a patient for the treatment of aphthous, these references fail to serve as the basis for a *prima facie* case of obviousness (see M.P.E.P. § 2143.03, *supra*). Accordingly, Applicant respectfully requests that the rejection of claims 1, 3, and 6 under 35 U.S.C. § 103(a) be withdrawn.

CONCLUSION

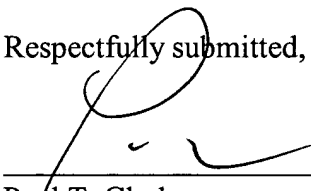
Applicant submits that the claims are in condition for allowance, and such action is respectfully requested.

Enclosed is a petition to extend the period for replying for four months, to and including May 26, 2005, and a check for the required fee under 37 C.F.R. § 1.17(a). If there are any other charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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